



FH

STATE OF WISCONSIN
Division of Hearings and Appeals

In the Matter of

[REDACTED]
[REDACTED]
[REDACTED]

DECISION

MPA- 173716

PRELIMINARY RECITALS

On April 15, 2016, the above petitioner filed a hearing request, under Wis. Stat. § 49.45(5), and Wis. Admin. Code § HA 3.03(1), to challenge a decision by the Division of Health Care Access and Accountability regarding Medical Assistance. The hearing was held on May 19, 2016, by telephone, from Madison, Wisconsin.

The issue for determination is whether the petitioner is entitled to medical assistance reimbursement for Davlinka and Sovaldi.

There appeared at that time the following persons:

PARTIES IN INTEREST:

Petitioner:

[REDACTED]
[REDACTED]
[REDACTED]

Respondent:

Department of Health Services
1 West Wilson Street, Room 651
Madison, Wisconsin 53703

By: [REDACTED], R. Ph. (written appearance only)
Division of Health Care Access and
Accountability
PO Box 309
Madison, WI 53701-0309

ADMINISTRATIVE LAW JUDGE:

Peter McCombs
Division of Hearings and Appeals

FINDINGS OF FACT

1. Petitioner (CARES #) is a resident of Vernon County.
2. On March 22, 2016, the petitioner with Wal-Mart Pharmacy requested a 24 week supply of a combined Davlinka and Sovaldi treatment. After reviewing the information provided by petitioner's provider, the Office of Inspector General denied the request on March 30, 2016
3. The petitioner is diagnosed with hepatitis C, genotype 1.
4. The petitioner has decompensated cirrhosis, with a Child-Turcotte-Pugh (CTP) score of B.
5. The petitioner is not on a liver transplant waiting list.
6. The petitioner has tested positive for esophageal varices, hepatic encephalopathy and portal hypertension.

DISCUSSION

Federal medical assistance rules allow, but do not require, states to pay for prescription drugs. 42 C.F.R. § 440.225. Wisconsin pays for prescription drugs (Wis. Admin. Code § DHS 107.10), but uses the discretion granted by the federal government to control their cost by dividing them into two classes, preferred and non-preferred. Preferred drugs are generally older, often generic, and generally less expensive than non-preferred drugs. Wisconsin requires prior authorization before paying for non-preferred prescription drugs, which it refers to as those it "has determined entail substantial cost or utilization problems for the MA program." Wis. Admin. Code, § DHS 107.10(2)(d).

The petitioner seeks payment from the medical assistance program for Daklinza and Sovaldi to treat his Hepatitis C. Daklinza and Sovaldi are non-preferred drugs requiring prior authorization when used to treat hepatitis C. The petitioner and his provider have must prove by the preponderance of the credible evidence that the drug is needed.

As with any request for a medical assistance service, the petitioner must prove, among other things, that the drug is medically necessary and appropriate. The Department must consider the cost of the service, the extent to which less expensive alternative services are available, and whether the service is an effective and appropriate use of available services. Wis. Admin. Code § DHS 107.02(3)(e)1.,2.,3.,6. and 7. "Medically necessary" means a medical assistance service under ch. DHS 107 that is "[r]equired to prevent, identify or treat a recipient's illness, injury or disability" and, among other things, "[w]ith respect to prior authorization of a service and to other prospective coverage determinations made by the department, is cost-effective compared to an alternative medically necessary service which is reasonably accessible to the recipient. Wis. Admin. Code, § DHS 101.03(96m)(a) and (b)8.

The department has developed guidelines on when to pay for Sovaldi. These guidelines, which are found in the department's online medical assistance handbook, Topic 17357, at

<https://www.forwardhealth.wi.gov/WIPortal/Online%20Handbooks/Display/tabid/152/Default.aspx?ia=1&p=1&sa=48&s=3&c=345&nt=Hepatitis%20C,%20Agents,%20Sovaldi&adv=Y>

allow the drug to be considered for those whose hepatitis C has advanced to any of the following stages:

* Compensated cirrhosis.

- * Metavir score of F3 or greater or evidence of bridging fibrosis.
- * HCC [hepatocellular carcinoma], if the member is on a liver transplant waiting list.
- * Serious extra-hepatic manifestations of HCV [Hepatitis C virus].

The drug must be prescribed by a “gastroenterologist or infectious disease provider practice,” and the recipient must be at least 18 years old. Sovaldi will be denied under the following circumstances:

- * The member has autoimmune hepatitis or other conditions that are contraindications for interferon or ribavirin.
- * The member has a significant or uncontrolled concurrent disease (e.g., depression, thyroid disease, diabetes, cardiovascular disease, pulmonary disease).
- * The member has decompensated cirrhosis.
- * The member has acute hepatitis C.
- * The member has received a liver transplant.
- * The member is currently abusing drugs or alcohol.
- * Non-compliance with approved hepatitis C treatment regimen (for renewals only).

Id.

The respondent indicated in its written submission that only PA requests for members with chronic hepatitis C genotype 3 infection will be considered for review. See, ForwardHealth Update 2015-50, Prior Authorization Drug Attachment for Hepatitis C Agents, F-01247 (8/15)). Additionally, pursuant to Prior Authorization guidelines, Daklinza as a combined treatment with Sovaldi will be denied where an individual has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C). (Note: If the member is currently on a liver transplant wait list with an elevated Model for End-Stage Liver Disease score, individual circumstances will be considered for review). Id.

Petitioner’s condition does not qualify as genotype 3, nor does he avoid denial due to his CTP class B score. Sovaldi undoubtedly would help those with Hepatitis C by preventing the complications from becoming more severe. But this knowledge must be viewed in the context of the high cost of the drug, the need for the medical assistance program to treat all sorts of people with all sorts of medical problems, and the fact that because the state does not have to cover any prescription drugs it could end the prescription drug portion of the medical assistance program if it cannot control costs. Viewed in this context, the policy is reasonable, even if it does not provide the best possible medical care for all who have Hepatitis C.

The petitioner testified credibly, and submitted documentation from his provider (Gunderson Health System), that supports treatment with Davlinka and Sovaldi for genotype 1. However, I must determine his eligibility for the treatment regime according to whether he meets the criteria set by the department. Because he does not meet the valid guidelines established by the department, I must uphold its decision.

CONCLUSIONS OF LAW

The Office of Inspector General correctly denied the petitioner's request for Sovaldi because he has not shown by the preponderance of the credible evidence that he meets the department's guidelines that prove that the drug is medically necessary.

THEREFORE, it is

ORDERED

The petitioner's appeal is dismissed.

REQUEST FOR A REHEARING

You may request a rehearing if you think this decision is based on a serious mistake in the facts or the law or if you have found new evidence that would change the decision. Your request must be **received within 20 days after the date of this decision**. Late requests cannot be granted.

Send your request for rehearing in writing to the Division of Hearings and Appeals, 5005 University Avenue, Suite 201, Madison, WI 53705-5400 **and** to those identified in this decision as "PARTIES IN INTEREST." Your rehearing request must explain what mistake the Administrative Law Judge made and why it is important or you must describe your new evidence and explain why you did not have it at your first hearing. If your request does not explain these things, it will be denied.

The process for requesting a rehearing may be found at Wis. Stat. § 227.49. A copy of the statutes may be found online or at your local library or courthouse.

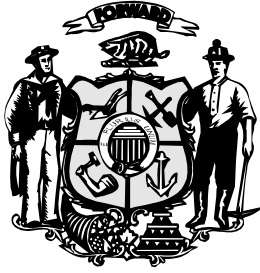
APPEAL TO COURT

You may also appeal this decision to Circuit Court in the county where you live. Appeals must be filed with the Court **and** served either personally or by certified mail on the Secretary of the Department of Health Services, 1 West Wilson Street, Room 651, **and** on those identified in this decision as "PARTIES IN INTEREST" **no more than 30 days after the date of this decision** or 30 days after a denial of a timely rehearing (if you request one).

The process for Circuit Court Appeals may be found at Wis. Stat. §§ 227.52 and 227.53. A copy of the statutes may be found online or at your local library or courthouse.

Given under my hand at the City of Madison,
Wisconsin, this 7th day of July, 2016

\s _____
Peter McCombs
Administrative Law Judge
Division of Hearings and Appeals



State of Wisconsin\DIVISION OF HEARINGS AND APPEALS

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The preceding decision was sent to the following parties on July 7, 2016.

Division of Health Care Access and Accountability